Autry Parker, M.D.

1. Qualifications:

I am an anesthesiologist and interventional pain management specialist and have been continuously licensed as a physician in Tennessee since 1992. I obtained my undergraduate degree from Howard University in Washington, D.C. in 1983. I then obtained both a Master's degree in Public Health from Yale University School of Epidemiology and Public Health and a medical degree from Yale University School of Medicine in New Haven, Connecticut in 1988. From 1988 to 1989, I completed an internship in the Departments of Surgery and Internal Medicine at the Hospital of Saint Raphael in New Haven, Connecticut. I then completed a residency in anesthesiology and critical care medicine, as well as a fellowship in pain management and regional anesthesiology at Johns Hopkins University Hospital in Baltimore, Maryland from 1989 to 1992. I have been certified by the American Society of Anesthesiologists since 1994, by the American Academy of Pain Management since 1992, and by the American Board of Pain Medicine since 1998.

From 1992 to 1995, I worked for Anesthesia Partners of Johnson City in Johnson City, Tennessee. During that time frame, I served as the Associate Medical Director for five months, during which I established a hospital based anesthesia department at Johnson City Medical Center Hospital. I also served as the Medical Director and Founder of the Center for Pain Management at JCMCH in Johnson City, Tennessee, a multidisciplinary, chronic pain management program.

From 1995 to 1996, I worked for Pain Care, Inc. in Memphis, Tennessee, where I served as the Interim Medical Director of the Pain Care Center at Saint Francis

Hospital. My responsibilities as the Interim Medical Director of that pain center included consulting and signing off on medication purchasing decisions.

From 1996 to 2010, I worked for Pain Services, P.C. in Memphis, Tennessee, where I served as the Medical Director of Parker Pain & Rehab Center, a multidisciplinary pain clinic emphasizing the treatment of acute and chronic spinal pain, cancer pain, and injured workers. My responsibilities as the Medical Director of that pain center included consulting and signing off on medication purchasing decisions.

Finally, since 2010, I have worked for Semmes Murphey Neurologic & Spine Institute ("Semmes Murphey") in Memphis, Tennessee, where I have served as an anesthesiologist and pain management physician on a team of physicians treating severe musculoskeletal pain, with an emphasis on spinal pain. During my time at Semmes Murphey, I have been consulted on medication purchasing decisions for the clinic by the nurses responsible for making those decisions, particularly in situations where the clinic has encountered a medication supply problem.

A copy of my *curriculum vitae*, more fully setting forth my experience and professional accomplishments, is attached as Exhibit 1. Any publications I have authored in the previous 10 years are listed on my *curriculum vitae*.

2. List of Cases

I have not testified as an expert at trial or by deposition in the past four (4) years.

3. Facts and Data Considered in Forming My Opinions:

In forming my opinions, I have generally relied on my education, training, experience, and the materials I have reviewed. The following is a brief summary of the facts I rely upon in forming my opinions regarding Saint Thomas Outpatient Neurosurgical Center ("STOPNC"), John Culclasure, MD, and Debra Schamberg, RN, CNOR.

a. Background for Howell Allen Clinic and STOPNC

Howell Allen Clinic and Saint Thomas Network, formerly known as Saint Thomas Health Services, opened STOPNC in 2000 as an ambulatory surgery center. Each entity owns 50% of STOPNC. When it opened, STOPNC was used almost exclusively as an operating room, performing occasional pain management procedures. In 2005, STOPNC began focusing on pain management procedures, and now, the facility does exclusively pain management. STOPNC is accredited by the Joint Commission as an ambulatory surgery center. Howell Allen is a neurosurgical group in Nashville which refers patients to STOPNC for pain management.

John W. Culclasure, MD is an employee-anesthesiologist at Howell Allen and STOPNC's Medical Director. Dr. Culclasure received his medical degree from the Medical University of South Carolina in 1983. He did his anesthesiology residency at Walter Reed Medical Center, and he served for six years and seven months on active duty in the U.S. Army Medical Corps as an officer, until his honorable discharge in 1990. After leaving the Army, Dr. Culclasure's practice continued to focus primarily on anesthesia for the next several years. In the early 90s, he began to practice more in

pain management, and his practice gradually shifted to focus almost entirely on pain management. Howell Allen hired Dr. Culclasure in 2005. He performs most of the pain management procedures at STOPNC. He has served as STOPNC's Medical Director since 2005. Dr. Culclasure is also an Adjunct Associate Professor for the Department of Anesthesiology at Vanderbilt University School of Medicine. Dr. Culclasure, in my opinion, is well-qualified to provide pain management services at STOPNC. He is also qualified as a physician to make decisions regarding the purchase of medications for a medical practice.

Debra Schamberg, RN, CNOR is STOPNC's Facility Director. Ms. Schamberg graduated from Tennessee State University School of Nursing in 1984. She was an OR nurse for the majority of her career. When she was hired by Howell Allen to work at STOPNC in 2000, she began to take on more management and administrative responsibilities, such as monitoring safety compliance, writing and revising policies and procedures, and teaching and orienting new employees. In 2005, when STOPNC began focusing on pain management, Howell Allen transferred Ms. Schamberg to the Center for Spinal Surgery, another facility in which Howell Allen maintains an ownership interest. At the Center for Spinal Surgery, she worked as an OR nurse, the OR Educator, the Infection Control Nurse, and the Employee Health Nurse. In May 2009, she became STOPNC's Facility Director. Ms. Schamberg's qualifications are sufficient, based on my experience and knowledge, to make purchasing decisions for medications (in conjunction with Dr. Culclasure) and to participate in the ordering process.

b. Medication Purchasing by STOPNC

STOPNC began purchasing from NECC in 2011. The primary reason STOPNC began purchasing from NECC was that NECC could provide a guaranteed supply of preservative-free MPA. In early to mid-2011, a representative from Clint Pharmaceuticals – STOPNC's provider of MPA – told Ms. Schamberg that there was a backorder or impending shortage of single-dose MPA. In the same timeframe, Dr. Culclasure was also interested in switching to MPA without preservative because of reports of adverse events following epidural steroid injections with preserved steroids. However, based on my review of the records and testimony, it appears the primary motivation in considering switching to NECC was to ensure a consistent supply of the medication at a competitive price.

In mid-2011, Ms. Schamberg, learned in her discussions with representatives of Clint Pharmaceuticals and/or CuraScript (suppliers of MPA) that MPA would be put on shortage or backorder status.

In 2010, Ms. Schamberg had met John Notarianni, a sales representative from NECC, a couple years before at a Freestanding Ambulatory Surgery Center Association ("FASCA") conference in Franklin, TN. NECC had a vendor's booth along with other well-known companies like BlueCross BlueShield of Tennessee, and Ethicon, a Johnson and Johnson brand. At the conference, Ms. Schamberg and Mr. Notarianni had a brief discussion regarding the products NECC offered to ambulatory surgery centers. At the conference, Mr. Notarianni provided Ms. Schamberg with printed literature about the services and medications that NECC could provide.

On or about May 4, 2011, around the same time that the Clint Pharmaceuticals representative told Ms. Schamberg of the impending problems with a steady supply of MPA, Mr. Notarianni called Ms. Schamberg, as he had every few months since 2010, to solicit STOPNC's business for NECC. Ms. Schamberg asked for pricing information for MPA and Omnipaque contrast dye. On May 4, 2011, Mr. Notarianni emailed Ms. Schamberg a pricing list for MPA and Omnipaque. Ms. Schamberg reviewed the pricing guide along with the other literature she had previously received from NECC. I have reviewed this literature, which explains NECC's facility, processes, and available products.

Mr. Notarianni represented to Ms. Schamberg that NECC would always be able to fill STOPNC's orders for MPA and that STOPNC would no longer have to deal with backorders or shortages. Mr. Notarianni assured Ms. Schamberg that NECC's facility was state-of-the-art.

Negotiations on price proceeded over the next month via emails and phone calls. NECC, through Mr. Notarianni, agreed to provide 1 mL vials for $6.50 per vial with minimum orders of 500 vials and 2 mL vials for $12.00 per vial with minimum orders of 200 vials. This price was slightly *more* than STOPNC had been paying for MPA from Clint Pharmaceuticals ($6.49 per 1 mL vial), its supplier at that time. CuraScript, STOPNC's other supplier, charged $7.02 per 1 mL vial, based on the materials I have reviewed.

After NECC agreed on the price, Ms. Schamberg discussed NECC with Dr. Culclasure. She explained that NECC had guaranteed a consistent supply of MPA and informed Dr. Culclasure that the MPA was preservative free. Dr. Culclasure approved

the switch to NECC. On June 10, 2011, Ms. Schamberg emailed Mr. Notarianni to accept NECC's terms.

STOPNC placed its first order for MPA from NECC on either June 10, 2011, or June 14, 2011.[1] NECC shipped the order on June 16, 2011. NECC was STOPNC's sole supplier of MPA from that point until the fungal meningitis outbreak in 2012.

Mario Giamei, another sales rep at NECC, visited STOPNC in early to mid-2012, after STOPNC had been ordering from NECC without any problem for several months, and spoke with Ms. Schamberg. He informed Ms. Schamberg that NECC needed STOPNC to submit a list of patients with each order to comply with Massachusetts law. Ms. Schamberg told Mr. Giamei that STOPNC would not be able to predict which patients would actually receive the MPA. Mr. Giamei said NECC only needed a list of STOPNC patients, not a list of the specific patients that were to receive the MPA. Mr. Giamei told her that the requirement came from the Massachusetts Board of Registration in Pharmacy.

Ms. Schamberg consulted with Dr. Culclasure prior to agreeing to send the list of names, and ultimately decided to supply NECC with a copy of STOPNC's daily patient schedule to comply with the request. Ms. Schamberg relied on Mr. Giamei's representation that the patient list was required by Massachusetts pharmacy regulations. Ms. Schamberg's hesitation about sending names was whether HIPAA was implicated.

Ms. Schamberg spoke with receptionist Sherri DeZwaan to determine the best way for STOPNC to generate such a list. Ms. DeZwaan suggested printing off the

[1] There appears to have been an error in transmission of the order on June 10, 2011, that was not discovered and remedied until June 14, 2011.

patient schedule. For the next several orders, when STOPNC needed to order MPA, Ms. Littleton, the nurse who placed the orders, asked Ms. DeZwaan to print off a list of names, which she did. On at least one occasion, Ms. DeZwaan was not at STOPNC when Ms. Littleton placed an order. Ms. Littleton submitted the order to NECC without a list of patients. NECC filled the order anyway.

STOPNC uses "placeholders" on its patient schedules to prevent double booking of Dr. Culclasure's time. Dr. Culclasure performs procedures at STOPNC's facility but conducts office visits at the Howell Allen Clinic. When he has a visit scheduled at the clinic, the staff at STOPNC uses a placeholder entry on the STOPNC schedule to ensure they do not schedule an appointment at STOPNC at the same time. A placeholder is necessary because STOPNC's patient scheduling system requires a medical record number to add anything to the daily schedule. Many of the patients who receive consults at Howell Allen do not have STOPNC medical record numbers because they are not STOPNC patients. STOPNC thus created "dummy" accounts to use as placeholders. "Mickey Mouse" and "Minnie Mouse" have been used as placeholders on STOPNC patient schedules for years prior to dealing with NECC because they are obviously not real patients, making it easy to immediately discern them from the real patients on the schedules.

When Ms. DeZwaan printed off the patient lists to send to NECC, she redacted the placeholder and consult patient's name from the lists. However, on one of the lists sent to NECC, Ms. DeZwaan overlooked one "Mickey Mouse" placeholder. I have reviewed nothing to suggest that STOPNC included "Mickey Mouse" on the patient

schedule sent to NECC to avoid any legal requirement or anything required by the standard of care.

STOPNC had no problems with any medication it received from NECC prior to the fungal meningitis outbreak in September 2012. Further, the orders STOPNC placed were delivered promptly and on-time. As promised, STOPNC no longer had to deal with shortages of MPA.

c. 2012 Meningitis Outbreak and Response

On September 18, 2012, Candace Smith, St. Thomas Hospital's Infection Control Nurse, called Ms. Schamberg while she was on vacation. Ms. Smith informed Ms. Schamberg that Vanderbilt University Medical Center ("VUMC") had called St. Thomas Hospital after a STOPNC patient had been diagnosed with meningitis and had a positive culture for *Aspergillus fumigatus*. Originally, the patient was admitted at VUMC and diagnosed with Rocky Mountain Spotted Fever and discharged. A few days later, on September 18, the patient presented to the emergency room at St. Thomas, and St. Thomas transferred him back to VUMC, where he was ultimately diagnosed with fungal meningitis.

Ms. Smith called Ms. Schamberg, at the request of the Tennessee Department of Health ("TN DoH"), to ask that she verify that the patient at VUMC was a STOPNC patient. Ms. Schamberg called Dr. Culclasure and asked him to confirm that the patient had received an epidural steroid injection at STOPNC. From that point forward, STOPNC worked closely and cooperated with the TN DoH to (1) identify the source of

the meningitis and (2) formulate an appropriate response. Ms. Schamberg and STOPNC followed the direction of the TN DoH in the response to the outbreak.

On Wednesday, September 19, 2012, another patient that received an epidural steroid injection at STOPNC presented to St. Thomas with symptoms of meningitis.

On Thursday, September 20, 2012, a third STOPNC patient presented to St. Thomas with symptoms of meningitis. STOPNC decided to temporarily suspend operations. STOPNC also sequestered all medical supplies that were used in any injections at the request of the TN DoH.

On Friday, September 21, 2012, Dr. Robert Latham, an infectious disease specialist at St. Thomas Hospital, Candace Smith, and Dr. Andrew Wiese from the TN DoH conducted a walk-through at STOPNC with Dr. Culclasure and Gretta Hallman, L.P.N., who frequently assisted with procedures at STOPNC. During the walk-through, the techniques used during epidural steroid injections were reviewed. After the review, the TN DoH concluded that any potential problems were likely not at the clinic level.

By Friday, September 21, 2012, there were five confirmed cases of meningitis. The TN DoH instructed STOPNC to "wait and see" what happened over the weekend. Two or three more STOPNC patients were admitted both days that weekend.

On Tuesday, September 25, 2012, the TN DoH instructed STOPNC to begin notifying patients of the potential exposure to contaminated medication. Initially, the TN DoH instructed STOPNC to call all patients who were seen at STOPNC on the same days as the patients already admitted for meningitis. The TN DoH specifically instructed STOPNC *not to mention meningitis* because the TN DoH, drawing from experiences in

the past, did not want to create a panic. Instead, the TN DoH instructed STOPNC to call patients and simply ask if they were doing okay.

On Thursday, September 27, 2012, the TN DoH expanded its instruction to STOPNC to notify all patients who were seen at STOPNC from July 2012 to September 2012. The TN DoH repeated the instruction that STOPNC was not to mention meningitis when calling patients. STOPNC complied. During the subsequent phone calls, any patient who thought he or she might be experiencing some sort of unusual symptom spoke with a nurse or physician at STOPNC. If the symptoms were even remotely unusual, the patient was instructed to report immediately to the nearest emergency room.

The TN DoH initially scheduled a press conference for Friday, September 28, 2012 to publicly announce the potential public health threat, but postponed it to Monday, October 1, 2012. On October 1, 2012, the TN DoH told STOPNC that they should start telling patients about fungal meningitis and advise them of the specific signs or symptoms for which they needed to be vigilant. The TN DoH allowed STOPNC to tell patients the outbreak of fungal meningitis was related to the recall of a steroid used during epidural steroid injections.

On October 1, 2012, STOPNC sent almost a thousand letters to patients who visited the facility from July 30, 2012 to September 20, 2012. On October 4, 2012 STOPNC sent approximately 125 letters to patients who visited the center in July, after the TN DoH extended the time period of concern back to July 1. Later, the TN DoH requested that healthcare providers, including STOPNC, send letters to patients via

certified mail. The TN DoH provided a draft letter, and STOPNC mailed it on or about October 9.

4. Materials

I have considered the following materials in forming my opinions:

- NECC advertising materials provided to STOPNC;
- NECC sales training video with Barry Cadden;
- Debra Schamberg, RN, CNOR's emails with NECC;
- Chart of STOPNC MPA Purchases from 2007 to 2013;
- NECC order forms and invoices;
- Patient lists sent to NECC;
- Patient schedules created prior to June 2011;
- New England Journal of Medicine Article Regarding the Fungal Meningitis Outbreak Authored by the Tennessee Department of Health;
- Letters to patients notifying them of potential contamination;
- Complaint from the *Reed* case;
- Articles cited by Plaintiffs as evidence of widespread reporting on the dangers of compounded medications;
- Preliminary Majority Staff Report from the House Committee on Energy and Commerce, titled, "FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?";
- New York Times article reporting on several Johnson & Johnson product recalls;
- STOPNC's formulary and policies & procedures regarding medication purchasing;

- US Compounding, Inc. voluntary recall; 2014-2015 FDA inspections of US Compounding, Inc.; 2012 and 2015 US Compounding, Inc. website printouts;
- NECC Customer List;
- 2012 STOPNC Joint Commission Accreditation Certificate;
- NECC emails regarding product representations to customers;
- Report from the 2011 Inspection of NECC by the Massachusetts Board of Pharmacy;
- October 14, 2011 Email from NECC sales representative to Orthopedic Clinic of Daytona Beach;
- February 22, 2012 email from NECC's head salesman (Robert Ronzio) to another salesman;
- Excerpts from an NECC training binder for sales personnel;
- Spreadsheet of drug recalls;
- Chart of site visits and supporting NECC documentation;
- Transcript of the deposition of Scott Butler;
- Transcript of the deposition of John Culclasure, MD;
- Transcript of the deposition of Debra Schamberg, RN, CNOR;
- Transcript of the deposition of Michael Cotugno;
- Transcript of the deposition of Francis McAteer;
- Transcript of the deposition of Jeff Ebel of Clint Pharmaceuticals; and
- Transcript of the deposition of Steve O'Neill.

I may review additional materials as appropriate, including any additional depositions taken in this matter. I may review the depositions of the Plaintiffs' Rule 26 witnesses and respond to opinions offered therein. I may review any additional

materials identified by the Plaintiffs' Rule 26 witnesses during their depositions and may respond with opinions, if indicated, regarding these materials.

5. Statement of My Opinions Regarding STOPNC:

a. Familiarity with the Standard of Care.

By virtue of my education, training, and experience as a anesthesiologist and pain management physician practicing in Memphis, Shelby County, Tennessee, I am familiar with the recognized standard of acceptable professional practice ("the standard of care") applicable to a health care provider purchasing a medication such as MPA in Memphis, Shelby County, Tennessee, as that standard existed in 2011 and 2012.

I have familiarized myself with Nashville, Davidson County, Tennessee by reviewing demographic information regarding that community. I have also personally visited Nashville, Davidson County, Tennessee on a number of occasions. Based on my training, my experience, and my familiarity with Nashville, Davidson County, Tennessee, I am familiar with the standard of care applicable to a health care provider purchasing a medication such as MPA in Nashville, Davidson County, Tennessee, or a similar community, as that standard existed in 2011 and 2012. Additionally, I believe that Memphis, Shelby County, Tennessee and Nashville, Davidson County, Tennessee are similar communities and that the standard applicable to a health care provider purchasing a medication such as MPA was the same in those communities in 2011 and 2012.

Based on my training, my experience, and my familiarity with Nashville, Davidson County, Tennessee, I am familiar with the standard of care applicable to a health care

provider purchasing a medication such as MPA in Nashville, Davidson County, Tennessee, as that standard existed in 2011 and 2012.

b. Discussion and Explanation of Medication Purchasing Decisions.

My testimony at trial will include discussion and explanation of medication purchasing decisions such as MPA from compounding pharmacies. I will discuss the factors that go into such decisions, including the consideration given to representations from a compounding pharmacy, consideration given to supply and demand of a particular medication, the role of medication cost in selecting a compounding pharmacy, the role of preservatives in selecting a medication to be used during an epidural steroid injection, the reliance on regulatory authorities such as the FDA and state pharmacy boards to police compounding pharmacies, the manner in which medications are ordered from a compounding pharmacy, and the use of patient lists in ordering medications from a compounding pharmacy.

c. Compliance with the Standard of Care

Stated succinctly, I believe it was appropriate and within the standard of care for STOPNC to purchase compounded MPA from NECC in 2011 and 2012. The following is a more detailed recitation of the factors supporting this opinion. All of my opinions are held to a reasonable degree of medical certainty.

i. STOPNC, Ms. Schamberg, and Dr. Culclasure Exercised Appropriate Due Diligence in Purchasing from NECC.

In my expert opinion, STOPNC and the involved employees and physician acted within the standard of acceptable practice and exercised appropriate due diligence in selecting NECC as its supplier of MPA. Prior to purchasing from NECC, Debra Schamberg, RN, CNOR obtained materials from NECC indicating that NECC was USP 797 compliant, that all medications prepared by NECC were formulated by properly licensed pharmacists extensively trained in aseptic compounding, that NECC used only USP quality ingredients in formulating medications, that NECC utilized a state of the art compounding facility and equipment, and that NECC followed a strictly-enforced environmental monitoring program and comprehensive end-product testing program, which included sterility and endotoxin testing by an independent laboratory. STOPNC had no reason to question these representations. All are reassuring to a purchaser of medications and none gave any indication that NECC could not and would not provide safe medications. Additionally, there were no guidelines from any major medical associations recommending any additional due diligence by an ambulatory surgery center prior to purchasing from a medication compounder such as NECC. The absence of any such guidelines reinforces the propriety of STOPNC's due diligence, prior to purchasing from NECC.

ii. STOPNC, Ms. Schamberg, and Dr. Culclasure complied with the Standard of Care by Purchasing from a Compounding Pharmacy.

It was reasonable for STOPNC to utilize a compounding pharmacy to supply it with MPA, and the standard of care did not require STOPNC to purchase MPA from a

drug manufacturer like Pfizer or Teva or Sandoz. There is no standard of care that bars the use of compounding pharmacies like NECC. There was no general belief in the medical community that compounding pharmacies were dangerous. Under the standard of care, compounding pharmacies were an appropriate and acceptable source of medications such as MPA in 2011 and 2012. The applicable standard of care does not prohibit a health care provider from purchasing an injectable steroid like MPA from a compounding pharmacy.

Likewise, under the applicable standard of care in 2011 and 2012, a provider was not required to view compounding pharmacies with any heightened degree of suspicion, or to consider them as a dangerous supplier of medications.

I have reviewed the materials cited by the Plaintiffs as evidence of pre-outbreak reporting on the dangers of compounded medications, including the December 13, 2002 CDC Morbidity and Mortality Weekly Report, the March 24, 2005 USA Today Article entitled "Safety Concerns Grow over Pharmacy-Mixed Drugs," the 2006 Limited FDA Survey of Compounded Drug Products, the 2007 FDA article entitled "The Special Risks of Pharmacy Compounding," the November 5, 2010 Summary Report from the Drug Shortages Summit with the ASHP Report Article entitled "ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems," a 2010 YouTube video posted by the FDA, and the May 4, 2012 CDC Morbidity and Mortality Weekly Report. The standard of care did not require Ms. Schamberg and Dr. Culclasure to be aware of this handful of materials before purchasing from NECC. Not one of these materials is from a source typically consulted by providers like Ms. Schamberg and Dr. Culclasure in making medication purchasing decisions at the time that STOPNC

purchased from NECC. Further, not one of these articles addresses NECC specifically or suggests that NECC was not a safe supplier of MPA. In my expert opinion, the standard of care did not require Ms. Schamberg and Dr. Culclasure to be aware of these articles at the time they elected to purchase from NECC, or to seek out these articles prior to purchasing from NECC.

The standard of care did not require STOPNC to purchase MPA from a drug manufacturer. The Plaintiffs suggest that drug manufacturers are safer than compounding pharmacies and that STOPNC should have selected a manufacturer, not a compounding pharmacy, as its supplier of MPA. This suggestion is misleading. Drug manufacturers are not immune from problems concerning the sterility of their manufactured medications and have issued drug recalls on numerous occasions, as indicated in the spreadsheet of drug recalls, which lists product recalls from a multitude of companies, including Pfizer, the well-known supplier of Depo-Medrol (brand name MPA). Notably, numerous recalls listed on the spreadsheet were the result of concerns about drug contamination, including the December 20, 2012 dexamethasone sodium phosphate injection recall from American Regent, the February 16, 2012 Cytarabine for injection recall from Bedford Laboratories, the August 14, 2012 propofol injectable emulsion recall from Hospira, Inc., and the February 13, 2014 etomidate injection recall from Pfizer-Mylan, to name only a few. Simply put, purchasing from a drug manufacturer does not provide any guarantee against problems with drug contamination. There is no way for a health care provider to ensure that the medication it receives is 100% safe, and buying from an "FDA manufacturer" does not do so.

Therefore, it is inaccurate to suggest that the standard of care required STOPNC to purchase from a drug manufacturer, not a compounding pharmacy.

The standard of care did not require STOPNC to purchase brand name MPA (Depo-Medrol) from Pfizer or the generic MPA. Under the standard of care, compounded MPA was a reasonable and acceptable alternative to Depo-Medrol, particularly in light of the Depo-Medrol shortage that had been communicated to Ms. Schamberg at the time STOPNC elected to purchase from NECC. Furthermore, Depo-Medrol is not preservative free, and Dr. Culclasure was reasonably and appropriately interested in procuring preservative free MPA, based on reports of adverse events following epidural steroid injections ("ESIs") with steroids that included preservatives.

iii. STOPNC's Formulary Did Not Preclude the Purchase of Compounded MPA.

STOPNC's formulary did not preclude STOPNC from purchasing the generic form of Depo-Medrol. STOPNC's formulary listed Depo-Medrol. Compounded MPA, like that provided to STOPNC by NECC, is the compounded equivalent of Depo-Medrol. Accordingly, by listing Depo-Medrol, STOPNC's formulary authorized the use of compounded MPA.

Lending further support to this conclusion, STOPNC's "Medication Substitution, Shortage, or Outage" Policy permitted the use of an acceptable medication substitution in the event of a shortage. Compounded MPA was an acceptable alternative to brand name Depo-Medrol. Moreover, STOPNC had previously purchased generic MPA manufactured by Sandoz from Clint Pharmaceuticals, without incident. It was reasonable to consider NECC's version of MPA to be like the generic equivalent of

Depo-Medrol. Finally, Medicare Part D encourages the use of generic medications. All of these factors support the conclusion that it was reasonable and appropriate for STOPNC to purchase compounded MPA, which is a reasonable equivalent to Depo-Medrol.

iv. The Standard of Care Did not Require STOPNC, Ms. Schamberg, and Dr. Culclasure to be Aware of the FDA and Massachusetts Board of Pharmacy Inspections of NECC.

The standard of care did not require STOPNC to be aware of the FDA and Massachusetts Board of Pharmacy inspections of NECC prior to purchasing from it, as none of those reports were published or generally available to the public prior to the outbreak. Regardless, the May 24, 2011 Massachusetts Board of Pharmacy inspection report revealed that NECC was a compliant and safe supplier of medications. Therefore, even if STOPNC had obtained the report, it would have had no reason not to buy from NECC after reviewing the report. The standard of care likewise did not require STOPNC to contact the Massachusetts Board of Pharmacy and the FDA regarding NECC prior to purchasing from it or to make any public records request. The Massachusetts Board of Pharmacy offers verification of licensees to the public via its website, which also includes a place for disciplinary actions. Prior to the outbreak, no disciplinary actions were noted for NECC. Accordingly, even if STOPNC had queried the website, it would not have resulted in the discovery of any disciplinary actions. Further, in order to obtain information from the FDA other than what is posted on its website (which, for NECC, was limited to the 2006 warning letter discussed below) a

formal request pursuant to the Freedom of Information Act must be submitted. The standard of care did not require STOPNC to submit any such request.

v. The Standard of Care Did not Require STOPNC, Ms. Schamberg, and Dr. Culclasure to be Aware of the FDA Warning Letter Issued to NECC.

The standard of care did not require STOPNC to be aware of the 2006 FDA warning letter issued to NECC. Under the standard of care, FDA warning letters are not documents that providers like Ms. Schamberg and Dr. Culclasure are required to consider when buying from a drug supplier. The standard of care did not require either Ms. Schamberg or Dr. Culclasure to query the FDA for any warnings or actions taken against NECC. Further, the mere fact that a medication supplier has received an FDA warning letter, or even been the subject of an FDA recall, does not preclude the use of that supplier. To suggest otherwise would inevitably result in the unreasonable exclusion of a large portion of the medication suppliers on the market. As noted above, numerous drug manufacturers have been subject to FDA recalls, for a variety of reasons. Moreover, since 2006, FDA warning letters have been issued to both Pfizer and Teva, two FDA-registered manufacturers of MPA. Sandoz, the third FDA-registered manufacturer of MPA, recalled more than 35,000 vials of MPA in 2010. Precluding health care providers from procuring medications from each and every supplier that has been subject to an FDA warning or recall would result in an unreasonably narrow list of potential medication suppliers. There were no "red flags" that Ms. Schamberg and Dr. Culclasure should have been aware of that would have caused a reasonable clinic to not buy from NECC.

Even if Ms. Schamberg and Dr. Culclasure had been aware of the 2006 warning letter, it would not have precluded purchasing MPA from NECC under the standard of care, because the warning letter did not pertain to MPA, the product STOPNC purchased from NECC, because the warning letter did not call into question the sterility of NECC's compounded medications, and because the warning letter was nearly five years old, with no public information of further action against NECC by the FDA. In fact, given the fact that NECC was still in operation five years after the letter was issued, it would have been reasonable for Ms. Schamberg and Dr. Culclasure to conclude that the problems triggering the letter had been resolved.

vi. It was Appropriate and in Compliance with the Standard of Care for STOPNC, Ms. Schamberg, and Dr. Culclasure to Rely on the FDA and/or Massachusetts Board of Pharmacy to Regulate NECC.

It was appropriate and in compliance with the standard of care for STOPNC to rely on the FDA and/or the Massachusetts Board of Pharmacy to monitor and regulate NECC, and to take action if NECC was utilizing unsafe practices in compounding sterile medications. Based on the fact that NECC was in operation in 2011 and 2012 with an active, unrestricted license, it was reasonable for Ms. Schamberg and Dr. Culclasure to conclude that it was in compliance with FDA and/or Massachusetts Board of Pharmacy regulations, and was operating within safe parameters.

vii. The Standard of Care did not Require STOPNC to Purchase MPA from an FDA-registered and/or PCAB-accredited Supplier.

The standard of care did not require STOPNC to purchase MPA from a supplier that was registered with the FDA and/or accredited by the Pharmacy Compounding Accreditation Board ("PCAB"). To suggest otherwise is misleading, as neither FDA registration nor PCAB accreditation is a guarantee against contamination problems, as demonstrated by the 2014 and 2015 FDA Inspection Observations of US Compounding, Inc. and the September 2015 US Compounding, Inc. recall US Compounding, Inc. is a PCAB-accredited, FDA-registered compounding pharmacy. Despite these certifications, in March 2014 and August 2015, inspections by the FDA resulted in multiple criticisms of US Compounding, Inc.'s sterility processes, including the following:

- Failure to wear proper protective apparel to protect against drug contamination (2014);
- Failure to establish procedures designed to prevent microbiological contamination of drug products (2014);
- Failure to maintain buildings used in the manufacture, processing, packing, or holding of drug products in a clean and sanitary condition (2014);
- Failure to employ container closure systems with adequate protection against external factors in storage and use that can cause deterioration or contamination of drug products (2014);
- Failure to utilize appropriate methods of cleaning and disinfecting equipment to produce aseptic conditions (2015);
- Failure to utilize appropriate methods of monitoring environmental conditions in aseptic processing areas (2015);
- Failure to utilize appropriate methods to ensure that air supply is filtered through high-efficiency particulate air filters under positive pressure in aseptic processing areas (2015); and,

- Failure to establish procedures designed to prevent microbiological contamination of drug products purporting to be sterile (2015).

viii. The Standard of Care did not Require a Site Visit to NECC.

The standard of care did not require STOPNC to perform a site visit at NECC's facility in Massachusetts. Of the thousands of providers who purchased from NECC, there is no evidence that anything more than a handful performed site visits. This proves that performing a site visit was not "standard." In all my experience purchasing from compounding pharmacies, I have never heard of a provider performing a site visit.

Moreover, even if STOPNC had performed a site visit, it is highly unlikely that it would have resulted in any concerns contraindicating purchasing from NECC, for several reasons. First, most clinicians such as Dr. Culclasure and Ms. Schamberg would not know what to look for during a site visit, as they do not have training in compounding processes. Accordingly, it is unlikely that either Dr. Culclasure or Ms. Schamberg would have recognized any concerning issues at NECC's facility, even if one had been present.

Additionally, even if STOPNC had retained an outside entity to conduct a site visit, it is unlikely it would have produced any concerning results. This conclusion is supported by the fact that Brigham & Woman's Hospital, in conjunction with Microbiological Research Associates, conducted site visits and audits of NECC in March 2008 and May 2012, both of which resulted in approval of NECC as a supplier of sterile compounded medications to Brigham & Woman's Hospital. The latter inspection is particularly notable, because NECC compounded the first lot of contaminated medications in May 2012, close in time to when the site visit and audit occurred. This

conclusion is further supported by the fact that the Massachusetts Board of Pharmacy conducted an inspection of NECC in May of 2011, which resulted in a finding that NECC appropriately met criteria for ongoing licensure in Massachusetts. If Brigham & Woman's Hospital, Microbiological Research Associates, and the Massachusetts Board of Pharmacy found no problems with NECC, it is highly unlikely that STOPNC would have found any. It appears that NECC had SOPs in place and had done the proper air testing. Even if Dr. Culclasure or Ms. Schamberg had decided to inspect SOPs or air testing results at NECC (assuming they even knew what to look for), they likely would have found everything in order, just as the evidence suggests the handful of inspecting customers did.

ix. The Standard of Care did not Require Investigation into Product Liability Suits against NECC.

The standard of care did not require STOPNC to investigate whether NECC had been the subject of a product liability suit before purchasing from it. At the time STOPNC purchased from NECC, a single plaintiff had filed a product liability suit against NECC in 2004, more than five years before STOPNC began ordering from NECC. In comparison, Pfizer, the manufacturer of Depo-Medrol (brand name MPA) had been sued by 35,000 plaintiffs around the same time. It is entirely unreasonable to suggest that a provider should refrain from purchasing medication from any supplier that had been the subject of a product liability suit. Were that true, it would result in an unreasonably narrow list of potential medication suppliers.

x. The Standard of Care did not Require Ms. Schamberg and/or Dr. Culclasure to Consult with a Pharmacist.

The standard of care did not require Ms. Schamberg and/or Dr. Culclasure to consult with a pharmacist not associated with NECC prior to making the decision to purchase from NECC. In my years of experience in making medication purchasing decisions, I have not typically discussed the purchasing decisions with any pharmacists other than those associated with the medication supplier from which I am purchasing. This is not a typical practice amongst health care providers such as STOPNC, Ms. Schamberg, and Dr. Culclasure.

xi. STOPNC, Ms. Schamberg, and Dr. Culclasure Appropriately Considered Medication Supply and Medication Price.

STOPNC acted appropriately and complied with the standard of care by taking into consideration NECC's ability to consistently supply MPA when deciding to purchase from NECC. In May or June of 2011, Ms. Schamberg learned that there was a shortage of MPA on the market through speaking with Clint Pharmaceuticals. In communicating with NECC through its representatives, NECC assured Ms. Schamberg that they could supply MPA in sufficient quantities to meet STOPNC's needs. It was appropriate and reasonable for Ms. Schamberg to factor this into the decision to purchase from NECC.

STOPNC acted appropriately and complied with the standard of care by taking into consideration NECC's ability to supply preservative-free MPA when deciding to purchase from NECC. Obviously, reducing the risk of adverse events in patients is an appropriate consideration when selecting medication. Dr. Culclasure reasonably

believed that using preservative-free medication would do so, based on reports of adverse events from ESIs using steroids containing preservatives.

STOPNC acted appropriately and in compliance with the standard of care by taking medication price into consideration when deciding to purchase from NECC. Prior to purchasing from NECC, STOPNC was purchasing MPA from Clint Pharmaceuticals at a rate of $6.49 per 1 mL vial. Around the same time that Clint Pharmaceuticals was unable to fill STOPNC's order in May or June of 2011, Clint Pharmaceuticals informed STOPNC that it was increasing the price to $8.95 per 1 mL vial, due to supply and demand, an increase which Clint Pharmaceuticals considered significant. STOPNC then secured an agreement from NECC to provide MPA at a rate of $6.50 per 1 mL vial or $12.00 per 2 mL vial.

When purchasing medication from medication suppliers, including pharmaceutical companies and compounding pharmacies, it is appropriate and within the standard of care for a provider to consider the cost of medication, and to endeavor to minimize that cost. In fact, medication pricing and the reduction of expenses are factors routinely taken into consideration by providers making medication purchasing decisions. Accordingly, it is appropriate and within the standard of care for a provider making a medication purchasing decision to take into consideration a medication supplier's ability to provide a medication at a lower price than a competitor. Here, it was well within the standard of care for STOPNC to take into consideration the fact that NECC was able to provide MPA at a cost comparable to what STOPNC had been paying for MPA, prior to the shortage and corresponding increase in cost by Clint Pharmaceuticals.

xii. Ms. Schamberg and Dr. Culclasure were Qualified to Make Medication Purchasing Decisions.

Ms. Schamberg and Dr. Culclasure had adequate experience and training under the standard of care to make medication purchasing decisions for STOPNC. First of all, in my years of experience, I have never heard of any formal training specifically for medication purchasing. As of 2011 and 2012, both Ms. Schamberg and Dr. Culclasure had years of experience making medication purchasing decisions and interacting with medication suppliers. Ms. Schamberg had been involved in purchasing decisions since 2009, when she became the Facility Director at STOPNC, and Dr. Culclasure had been involved in purchasing decisions since 2005, when he became the Medical Director at STOPNC. No additional, specific training in evaluating and purchasing from medication suppliers was required under the standard of care, given their experience level. Moreover, to criticize STOPNC for not providing additional training to Ms. Schamberg and Dr. Culclasure assumes that it was inappropriate to purchase from NECC which, as detailed in this report, is incorrect.

xiii. The Standard of Care did not Require Additional Policies and Procedures Regarding Medication Purchasing.

The standard of care did not require STOPNC to have any additional policies and procedures in place regarding the purchase of medications, other than those it had, including the Formulary Policy and the "Medication Substitution, Shortage or Outage" Policy, which adequately addressed the medications to be used at STOPNC, and acceptable substitutions in the event of a shortage. Moreover, criticizing STOPNC for failing to have additional policies and procedures in place regarding the purchase of

medications presumes that it was inappropriate for STOPNC to purchase from NECC which, as detailed in my report, is false.

xiv. The Standard of Care did not Require Informing Patients of the use of Compounded MPA.

The standard of care did not require STOPNC or Dr. Culclasure to inform patients that they were receiving compounded MPA during their procedures. Compounded medication is therapeutically equivalent to a medication manufactured by a drug company. Moreover, there was no reason for Dr. Culclasure to believe that the compounded MPA presented an increased risk. Furthermore, informing a patient of the identity of each medication used during a procedure, and whether each medication to be administered is a brand name medication, a generic, or a compounded medication is not a common or standard practice. In my experience, most patients would not appreciate or understand the difference, even if informed that they were receiving generic/compounded MPA versus brand name Depo-Medrol.

xv. NECC's Customer List Demonstrates Purchasing from NECC Complied with the Standard of Care.

In addition to the aforementioned factors, the propriety of STOPNC's decision to purchase medications from NECC is further supported by the fact that approximately 3,000 other health care providers and facilities, from across the United States, including more than 50 clinics, ambulatory surgical centers, and hospital facilities in Tennessee alone, purchased medications from NECC, as reflected by NECC's customer list. That customer list also included such notable facilities as the Emory University Hospital in

Atlanta, Georgia, Durham Regional Hospital at Duke, NYU Medical Center in New York, New York, Brigham and Women's Hospital in Boston, Massachusetts, and the University of California San Francisco Medical Center in San Francisco, California. The mere fact that such a large number of clinics, ambulatory surgical centers, and hospitals purchased from NECC demonstrates that it was appropriate and in compliance with the standard of care for STOPNC to purchase from NECC.

xvi. STOPNC's Uneventful Use of NECC Compounded MPA Prior to the Outbreak Reinforces the Propriety of the Decision to Purchase from NECC.

In addition to the aforementioned factors, the fact that STOPNC performed over 4,000 procedures using NECC compounded MPA without incident reinforces the propriety of STOPNC's decision to purchase from NECC. Stated another way, based on the fact that over 4,000 procedures using NECC compounded MPA were performed at STOPNC without incident, it was reasonable for STOPNC to believe, in an ongoing fashion, that NECC was a safe provider of quality MPA, and to continue purchasing from NECC until the outbreak.

xvii. The Standard of Care did not Require Individual Patient Specific Prescriptions.

The standard of care did not require STOPNC to submit individual, patient-specific prescriptions when purchasing MPA from NECC. At the time, there was no state or federal law governing ambulatory surgery centers that required STOPNC to submit individual patient-specific prescriptions when purchasing medication. The only arguably relevant regulations applied to NECC, not STOPNC. STOPNC, an ambulatory

surgery center, had no reason to be familiar with regulations applicable to pharmacies. Moreover, it was reasonable for STOPNC to rely on NECC to accurately inform it of the laws and regulations governing purchasing MPA from a compounding pharmacy like NECC, including whether patient-specific prescriptions were required. There was no reason for STOPNC to question NECC's request for lists of patient names. Additionally, the supply of patient names in no way caused any injury to the patients. The same medication would have been sent to STOPNC whether they provided a list of patient names, no patient names, or individual prescriptions.

6. Exhibits:

I reserve the right to utilize the documents identified in Section 4 above to summarize or support my opinions, as well as anything produced in discovery.

7. Compensation:

I charge $750 per hour for record review, depositions, and testimony at trial. I also require reimbursement of travel expenses. To date, I have been compensated $0 for my expert services in this matter, as I have not yet submitted an invoice. However, I have 4 hours of unbilled time. My compensation is in no way contingent on the outcome of the case.

Autry Parker, M.D.

01/08/2016

Date